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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/574,687
Filing Date: April 05, 2006
Appellant(s): MORITA ET AL.

Jerrick J. Ho
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 29, 2011 appealing from the Office action mailed November 26, 2011.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1, 3-7, 9 and 18.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN

REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,324,591	Georger, Jr. et al.	6-1994
6,294,313	Kobayashi et al.	9-2001
5,776,748	Singhvi et al.	7-1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-7, 9 and 18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Georger et al. (US PAT. 5,324,591) in view of Kobayashi et al. (US PAT. 6,294,313) and Singhvi et al. (US PAT. 5,776,748).

Georger et al. teach a method of culturing cells such as endothelial cells on patterned surfaces (ultra-thin film; UTF) having the selective adhesion formed by patterned irradiation (Abstract; Fig. 1; col. 3-4; col. 13, lines 5-8).

The UTF of Georger et al. is formed on a glass plate coated with EDA (N-(2-aminoethyl-3-aminopropyl) trimethoxysilane; aminosilane), and upon the irradiation through a shield (a mask), the EDA in the unshielded regions results in photochemical modification producing a pattern of oxidized surface molecules, and the oxidized surface of unshielded region is coated with 13F. The resulting EDA/13F UTFs would have a patterned surface with the EDA region (first region; cell adhesive region) having the water contact angle of EDA (28-32°), that is cell adhesive regions, and the 13F coated region (second region; cell non-adhesive region) having the water contact angle of 13F (92-94°), that is cell non-adhesive regions (col. 4, line 65 through col. 5, line 2). Thus, this teaching meets the limitation of water contact angles being between 10 and 40°.

With regard to the first region (cell adhesive region) arranged on the second region (cell non-adhesive region), Georger et al. also teach that a "pattern UTF" can be prepared, for example, irradiation reactive material such as chlorosilane or methoxysilane can be exposed and then a second silane can be built up selectively in the most reactive areas (col. 6, lines 25-28). Since Georger et al. teach that chlorosilane or methoxysilane is cell adhesion inhibitory (col. 14, lines 39-51), the second amine would be cell adhesive, and Georger et al. teach aminosilane being cell adhesive (e.g. EDA; col. 14, lines 25-38). Therefore, this configuration would be with the cell adhesive region formed with cell adhesive material (aminosilane) onto the cell non-adhesive region coated with cell adhesive inhibitory materials (chlorosilane or methoxysilane).

With regard to the pattern of the first region being linear, according to the Figure 3 of Georger et al., the pattern formed on the UTF is linear, satisfying the limitation of the first region (cell adhesive region) being linear.

Georger et al. do not teach a step of transferring the adhered cells to a cell culture substrate in the patterned state.

Singhvi et al. teach a step of transferring cells grown in pattern on hydrophobic/biophilic surface (a primary plate) made of self-assembled monolayer (SAM) such as silicone elastomers including polydimethylsiloxane (PDMS) to a secondary plate having a biophilic SAM with a higher binding affinity for the desired cell or cells than the biophilic SAM on the primary plate (col. 18, lines 12-37).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use the transferring step taught by Singhvi et al. for the cells adhered on cell adhesive UTF of Georger et al. to a secondary substrate.

The skilled artisan would have been motivated to make such a modification because one skilled in the art would recognize that the transferring step can be useful in order to prepare cellular implants having a patterned state since the patterned cells adhered onto the cell adhesive UTF of Georger et al. are intended as implants (col.4, lines 1-3). For example, cells adhered onto the UTF of Georger et al. can be transferred to another substrate (e.g. culture plate with higher affinity) intended for implantation (artificial organ, device, etc.), or to the substrate which already contains second type of cells in a patterned state in order to form implants having multiple cell types (co-culture system) or in order to have multiple cells on the surface of implantable or prosthetic device or organs, or simply one can use a second culture plate for temporary culturing the adhered cells prior to preparing implants.

Therefore, one skilled in the art would certainly try the transferring step of Singhvi et al. for the further manipulation of the patterned cells of Georger et al. with a reasonable expectation

of success.

With regard to the limitation of the cell adhesive variation layer comprising a cell adhesiveness variation material whose cell adhesiveness is varied by the action of a photocatalyst along with energy irradiation (claim 3), the UTF substrate of Georger et al. is considered as the cell adhesiveness variation layer that is coated with either cell adhesive silane (e.g. aminosilane), and upon irradiation with a mask, irradiated region of the cell adhesive variation layer is changed (see Fig. 1).

While Georger et al. do not particularly use the term "photocatalyst", the UTF of Georger et al. can contain a surface layer comprising inorganic materials such as titanium oxides (TiO_2) (col. 6, lines 38-53), and Kobayashi et al. teach that TiO_2 is a photocatalyst activated by UV irradiation (col. 13, lines 32-40) used in the reaction modifying the surface coated with silane with alkyl chains to OH groups upon irradiation in the presence of a photocatalyst, and thereby changing wettability of the surface (see Fig. 1; col. 19, lines 46-60).

Therefore, one skilled in the art would recognize the property of TiO_2 as a photocatalyst and the use of TiO_2 in pattern formation as taught by Kobayashi et al., and therefore, it would have been obvious to a person of ordinary skill in the art to use TiO_2 as a photocatalyst in pattern forming on a substrate of Georger et al., particularly when Georger et al. teach that TiO2 can be a part of the pattern forming substrate.

With regard to the order of layers as disclosed in claim 5 or the orientation of layers (cell adhesiveness variation material and the photocatalyst-comprising layer facing each other) as in claim 6, these limitations are not required for the process steps claimed in claim 1. Claim 1 is directed to steps of adhering cells on the patterned substrate having cell adhesive (first region)

and cell non-adhesive (second region) regions, and transferring the cells from the first region to another cell culture substrate. Whether or not the patterned substrate has a specific order or orientation of layers, it does not limit the claimed process unless there is unexpected and surprising results derived from the specific order of the layers. Therefore, it would have been obvious to a person of ordinary skill in the art to try various different arrangements of the layers coated on the substrate.

With regard to the cell culture substrate (second plate) being made of a biomaterial, the term "biomaterial" is interpreted as any matter, surface or construct that interacts with biological systems. Since the second plate being used in the transferring steps of Georger et al. in view of Singhvi et al. can be a surface of prosthetic or implantable devices according to Singhvi et al. (see col. 21, lines 10-22), the prosthetic or implantable devices are considered to be made of a biomaterial.

With regard to the limitation in claim 9 of the widths and the distance (space widths between lines), Georger et al. teach the width of the first region (cell adhesive UTF region) being 40 μm wide (col. 5, lines 2-20; Fig. 3). Furthermore, it is considered that the specific sizes of each line formed on the substrate and the distance between such lines are result-effective variables. In support, Georger et al. teach the use of endothelial cells and the patterning would be achieved by coating with at least one region of cell adhesion promoter with a width which corresponds to the desired outer circumference of the microvessel (col. 9, lines 56-63). Therefore, the arrangement of the regions having cell adhesiveness and the regions cell non-adhesiveness would be optimized based on the desired purpose of the cell patterning device by routine experimentations.

Generally, differences in sizes and distances will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382; In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

With regard to the limitation of claim 18, according to Fig. 3A of Georger et al., there are two different types of first regions (cell adhesive region having two different widths; dark regions) and two different types of second regions (cell non-adhesive region having two different widths; white regions). Furthermore, it would have been obvious to a person of ordinary skill in the art to try two or more types of cells on multiple first regions and second regions of the substrate of Georger et al. The skilled artisan would have been motivated to make such a modification because Georger et al. teaches that the apparatus can be used for neuronal or neuromuscular synapse formation having neuron and muscle cells adhered to the different areas of the promoter region (col. 9, line 64 through col. 10, line 6).

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

(10) Response to Argument

Appellant argued that the Examiner has not provided the basis supporting the determination that Georger inherently teach a step of transferring cells grown on UTF upon the contact with the organ. While the previous OA discusses the inherent teaching of Georger et al. for the limitation of transferring step, however, it is noted that the Examiner no longer relies on the inherency argument.

Appellant alleged that Singhvi does not teach or suggest the claimed step of transferring cells **in the patterned state** as recited in Claim 1. Appellant argued that Singhvi teaches the transfer of one or more cells from a library to a secondary plate. Further, Appellant asserted that Singhvi is directed to transferring a plurality of individual cells (each of technically differing character) onto a secondary plate in a manner that one of ordinary skill in the art would not consider to be "a patterned state". Still further Appellant asserted that Singhvi teaches a cell retrieval system (col. 18, line 19) that provides for contacting a secondary plate at a specified island having specified coordinates for retrieval.

In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The teaching of Singhvi et al. combined with the teaching of Georger et al. is the step of transferring cells adherent to a first plate in a patterned state to a second plate, and such transferring is mediated by the higher binding affinity to the desired cell or cells in the second plate than the binding affinity on the primary (first) plate.

By combining the teaching of Georger et al. directed to the cells in patterned state with the teaching of Singhvi et al. directed to the transfer step would allow one skilled in the art to transfer the cells adhered to the first plate of Georger et al. which is in the linear patterned state to the second plate. One skilled in the art would recognize the transfer step of Singhvi et al. is useful as a temporary step prior to the preparation of desired implant device having cells adhered in patterned state. The temporary step can be a passaging of the cells during the culture, changing the substrate for a desired purpose, or preparing an implantable device, or an artificial or a natural organ for transplantation.

Appellant's argument was focused on the one embodiment disclosed by Singhvi et al. that a single cell from one of multiple patterned islands formed on the first plate can be retrieved to a secondary plate, and such single cell retrieval cannot be considered as transferring in a "patterned state". The Examiner acknowledges that a single cell being retrieved from the primary plate having multiple islands onto the secondary plate might not be considered as "patterned", if there is no other cells being transferred along with it. However, as discussed in the earlier OA, Singhvi et al. not only disclose a single cell transfer but also they teach that more than one island on the primary plate can be transferred onto the secondary plate with biophilic SAM islands corresponding spatially to them (see below).

> "In addition, secondary plates could be produced which would retrieve more than one cell by constructing a secondary plate with biophilic SAM islands corresponding spatially to more than one island on the primary plate. Further, to enhance transfer of the desired cell or cells from the primary plate to the secondary plate, it may be desirable to have larger islands of biophilic SAM on the secondary plate or to use a biophilic SAM on the secondary plate with a higher binding affinity for the desired cell or cells than the biophilic SAM on the primary plate." (col. 18, lines 8-12 of Singhvi et al.)

This disclosure should be interpreted that multiple cells from multiple patterned location (islands) are transferred to the secondary plate having islands spatially corresponding to those of

the first plate, and thus the original coordination of each cell relative to other cells in the patterned state of the primary plate being replicated or copied onto the secondary plate with the same coordination. When these "more than one cell" being retrieved from the first plate already have a patterned state with specific coordination, and if these cells are transferred to the second plate having the identical spatial coordination of the first plate, then the spatial coordination of the cells of the first plate would be maintained in the second plate. Thus, it is considered that the transfer step of Singhvi et al. per se teaches the transferring cells in a patterned state.

Upon the combination of the teaching of Singhvi et al. with Georger et al., one skilled in the art would try to transfer cells formed in patterned state on the first plate of Georger et al. to the second plate, and when all or most of the cells adhered onto the first plate being transferred to the second plate, and thus replicating the coordination/pattern of the first plate onto the second plate, such transfers should be considered in patterned state.

With regard to the Examiner's characterization of Singhvi with respect to "generating surfaces for this culture, creation of artificial tissues for grafting or implantation, for generation artificial tissues to adhere to the surfaces of prosthetic or implantable devices" and the Examiner's assertion that the patterned cells can be transferred to the surfaces of prosthetic or implantable devices, Appellant alleged that this is based on the disclosure of Singhvi et al. at column 20, lines 27-30 that is directed to "patterned proteins", and concluded that Singhvi et al. do not teach or suggest how to transfer a linear cell pattern into the surfaces of prosthetic or implanted devices or tissue culture plates. Appellant asserted that Singhvi et al. teach away from transferring a linear cell pattern onto a second surface, and one of ordinary skill in the art would not have modified the cited references as alleged.

It is noted that the passage of Singhvi et al. cited by Appellant ("patterned protein") has not been used in the OA, rather the Examiner utilized the disclosure of Singhvi et al. at the column 21, lines 10-22, where Singhvi et al. discussed the use of plates of patterned cells in various applications including use in tissue culture, creation of artificial tissues for grafting or implantation, use in artificial organs, and generating artificial tissues to adhere to the surfaces of prosthetic or implantable devices.

Even if it is considered to direct "patterned proteins", Singhvi et al. further teach the use of patterned proteins for cells to adhere to the patterned proteins to form a plate of patterned cells (see col. 20, lines 57-60).

Singhvi et al. are clear that the plate may be a prosthetic or implantable device on which it is desired to form a SAM or adhere patterns of cells, proteins, or other biological materials (col. 7, lines 43-46). Thus, the second plate of Singhvi et al. for the transfer step can be any surface desired for the intended purpose of the patterned cells (e.g. surfaces of prosthetic, implantable devices, culture plates, etc.).

Appellant disagrees with the reasons for combining Georger and Singhvi for the following reasons: (1) one skilled in the art would not have applied the step of transferring individual cells to the teaching of Georger; (2) one skilled in the art would readily appreciate the fundamental difference between outgrowth in a cell culture and segregation of individual cells; (3) Singhvi teaches away from the detachment of cells adhered to each other in sheets.

Appellant is focused on one embodiment of Singhvi et al. directed to retrieving a single cell from a single island from the first plate and transferring the single cell to the second plate, and concluded that the transferring step of Singhvi et al. is useless when cells are not identifiably

segregated on the islands of the primary plate. First, the intended purpose of Singhvi's embodiment is to retrieve individual cells from the first/primary plate, and in order to carry out such isolated retrieval of cells, one needs to prepare the primary plate with individual cells segregated sufficient enough to allow individual cell transfer. However, this embodiment would not teach away one skilled in the art to use the transfer step for multiple cells in various different patterns on the first plate to the second plate. While Singhvi et al. disclose segregation of cells into each individual island on the first plate, however, it is submitted that this particular configuration is not required for the transferring step of Singhvi et al. In other words, the transferring step of Singhvi et al. does not require that cells have to be segregated into individual islands on the first plate. With any predetermined pattern or even without any pattern, cells adhered on the first plate can be transferred to another plate when there is stronger cell binding affinity on the surface of the second plate than the first one. Whether single cell or multiple cells, or even entire cells on the first plate being transferred to the second plate, it is a matter of how the cell binding surfaces of the second plate is designed based on the intended purpose of the resulting product. Therefore the segregation of cells in the first plate is not a prerequisite for transferring cells to the second plate. Considering this analysis, one skilled in the art would not consider that the patterned cells of Georger et al. need to be segregated into individual cells in order to transfer the cells to the second plate using the transferring step of Singhvi et al.

Still further, it is submitted that Georger et al. disclose that individual cells can be patterned. In col. 7, lines 59-63, Georger et al. teach the substrate pattern is designed to position individual or groups of cells. Thus, it is submitted that Georger et al.'s teaching is not confined to

multiple groups of cells, but it also includes individual cell when it is necessary for the intended use of the resulting patterned cell substrate.

Appellant alleged that Georger et al. is directed to the outgrowth of cells in a cell culture whereas Singhvi is directed to segregation of individual cells, and thus they are fundamentally different. The Examiner respectfully disagrees with this conclusion.

Georger et al. teach that the patterned substrate is useful for cellular outgrowth, and it is construed that the patterned substrate provides the guidance and/or direction of the outgrowth. The island pattern of Singhvi et al., however, is not for outgrowth of cells, and therefore, Appellant concludes that these two different intended purposes would teach away from combining the two references. It is acknowledged that the shape or design of the preferred pattern disclosed by Singhvi et al. (grid pattern with islands; Fig. 1) is different from that of Georger et al. (linear pattern; Fig. 3 and 4). However, the question to ask here is whether the pattern of Georger et al. that is useful for outgrowth of cells would teach away or prevent one skilled in the art using the transferring step for retrieving individual cells as taught by Singhvi et al. merely because the design/shape of pattern is different from that disclosed by Singhvi et al. It is submitted that the shape or design of the pattern formed on the substrate can be modified into any shape or design for the intended purpose of the patterned cells. Even if Georger et al.'s patterned substrate is intended for outgrowth whereas the Singhvi's patterned substrate is intended for segregation of cells, these different patterns are not sufficient enough to prevent one skilled in the art combining the transferring step of Singhvi et al. with the method of Georger et al.

The Appellant's intention with regard to the third reason is not clear. Appellant stated that given the objective of Singhvi for adhering cells in a specific and predetermined position, detachment of cells in large sheets from the substrate is disparaged. The Examiner does not clearly understand what point Appellant intends to make in this argument. The instant claims do not disclose any limitation about the size of substrate, and the Examiner's rejection is not based on the size of the substrate.

With regard to the "obvious to try" rationale, the Examiner concluded that it would have been obvious for the person of ordinary skill in the art at the time the invention was made to use the transferring step taught by Singhvi et al. for the cells adhered on cell adhesive UTF of Georger et al. to a secondary substrate. The Examiner stated that the skilled artisan would have been motivated to make such a modification because one skilled in the art would recognize that the transferring step can be useful in order to prepare cellular implants having a patterned state since the patterned cells adhered on to the cell adhesive UTF of Georger et al. are intended as implants (col.4, lines 1-3). For example, cells adhered onto the UTF of Georger et al. can be transferred to another substrate (e.g. culture plate with higher affinity) intended for implantation (artificial organ, device, etc.), or to the substrate which already contain second type of cells in a patterned state in order to form implants having multiple cell types (co-culture system) or in order to have multiple cells on the surface of implantable or prosthetic device or organs, or simply one can use a second culture plate for temporary culturing the adhered cells prior to preparing implants. Based on this discussion, it is submitted that the Examiner provided a rationale to combine the teaching of Singhvi et al. with that of Georger et al.

Appellant alleged that Singhvi et al. does not teach "linear" cell adhesive regions. Appellant appears to interpret the "linear" limitation too narrowly. While the linear pattern of Georger et al. is a continuous line, however, the term "linear" in the claimed invention does not require the pattern to be a continuous line configuration. The islands on the grid pattern of Singhvi et al. are also considered as linear. Singhvi et al. teach the method of preparing a patterned plate with a grid pattern using a stamp fabricated to have a linear indentation pattern contiguous with a linear stamping surface pattern, and the resulting pattern included parallel SAM lines of two microns in width (see Example 3). Therefore, the island pattern of Singhvi would be considered as a linear pattern.

Even if it is considered that the pattern of Singhvi is not linear, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Georger et al. clearly disclose the pattern being linear, and upon the combination of two teachings, the linear patterned cells of Georger et al. would be transferred to the second plate in patterned state by using the transferring step of Singhvi et al.

Appellant also argued that Singhvi teaches away from transferring a cell pattern cultured on a linear cell-adhesive regions, and cited col. 12, line 62 to col. 13, line 1. The Examiner respectfully disagrees with the analysis of the cited passage from Singhvi et al. In the cited paragraph, there is no information with regard to the linear pattern, rather it is focused on the island pattern, and the size of island that contacts with cells be smaller in order to easily remove cells from the plate either for elution or for replica plating. It is understood that the smaller

contact area for cells to the UTF or SAM is better or easier for removing the cells from the plate based on the Singhvi's disclosure. Appellant interpreted that the linear pattern of Georger et al. would have inevitably larger contact area compared to the island pattern of Singhvi, and thus it is difficult to retrieve or remove cells on the linear pattern compared to island pattern. There is no evidence to conclude that the linear pattern would have a size that is inevitably much larger than islands.

The width of linear pattern of Georger et al. can be modified (see Fig. 3), and Georger et al. teach that the EDA lines (cell adhesive region) are 12 μm wide, and the spatial resolution of the alternating EDA/13F patterns was finer than the spheroid cell diameters, and this caused the cells to immediately elongate and adopt a morphology corresponding to the shape of the patterned EDA while minimizing interaction with the surrounding 13F surfaces (col. 19, lines 12-19). Thus, the contact area formed with the linear pattern having 12 μm in diameter cannot be concluded to be much larger than that of the islands which can be modified empirically.

Georger et al. teach the modification of diameter/width of patterned lines for cell adhesion, and Singhvi discloses that the appropriate size of island is generally determined empirically without undue experimentation (col. 12, lines 33-62). One skilled in the art would understand that the patterns can be modified in their size. Based on the paragraph from Singhvi cited by Appellant, one skilled in the art would recognize the benefit of having smaller contact area of the patterned substrate with cells in transferring cells. Therefore, one skilled in the art would certainly modify the diameter/width of the linear pattern of Georger et al. to have smaller contact area in order to facilitate the transferring step.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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